

**ASSESSMENT OF NON-PHARMACOLOGIC PATIENT-CENTERED PAIN CONTROL
ADJUNCTS ON PAIN SCORES DURING FIRST TRIMESTER ABORTION**

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ABSTRACT

Objectives: The objective of this study is to review the literature regarding non-pharmacologic pain management techniques during first trimester abortion and to determine if a patient-centered approach to non-pharmacologic pain management is associated with lower pain scores during a first-trimester surgical abortion.

Study Design: Chapter one contains an integrative review of the literature regarding predictors of pain during first trimester abortion and of the efficacy of non-pharmacologic pain management techniques. Chapter two presents a randomized controlled trial of a patient-centered non-pharmacologic pain management approach during first trimester surgical abortion.

Results: The integrative review found that pre-procedure anxiety and depression are associated with increased pain during first-trimester surgical abortion. The trials of non-pharmacologic pain management techniques found that none of the interventions had a significant impact on pain scores during the procedure. The randomized controlled trial presented in Chapter Two found no difference between the intervention (patient-centered non-pharmacologic pain management) and control (standard care) groups.

Conclusions: Anxiety, depression and isolation have consistently been shown to be a good predictor of patient pain levels during first-trimester surgical abortion. The studies in the integrative review and the randomized controlled trial attempted to mitigate these impacts through non-pharmacologic pain management techniques. While none of the trials demonstrated an association between these techniques and reduced pain scores,

patients were consistently positive about the use of these techniques. Adding these interventions to clinical practice could be a low-cost, low-risk quality improvement measure.

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LIST OF ABBREVIATIONS

CI- Confidence Interval

CONSORT- CONSolidated Standards of Reporting Trials

EVA- Electric Vacuum Aspirator

MVA- Manual Vacuum Aspirator

NRS - Numerical Rating Scales

NSAID- Non-steroidal Anti-Inflammatory Drug

OR – Odds Ratio

PGY- PostGraduate Year

RCT- Randomized Controlled Trial

SD- Standard Deviation

STAI- State-Trait Anxiety Inventory

VAS- Visual Analog Scales

CHAPTER ONE: BACKGROUND AND LITERATURE REVIEW

I. Background

First trimester aspiration, or surgical, abortion is a common office-based procedure. Approximately 91.4% of abortions performed in the United States take place in the first-trimester, with the majority occurring as office- or clinic-based aspiration procedures.^{1,2} Abortion is safe procedure, with a lower mortality rate and a lower incidence of serious complications, including lower incidence of mental health conditions, hemorrhage and infections, than childbirth.^{3,4}

Patients commonly report moderately severe pain during office-based abortion.^{5,6} While the use of analgesic and anesthetic agents during office-based surgical abortion is common, these medications add cost and risk to the procedure. Anesthesia was the factor most commonly associated with mortality during abortion in the first 25 years after *Roe v Wade*.⁷ Advancements in clinical practice since that time have made significant improvements in patient safety, but recent studies found that 22% of deaths during first trimester surgical abortion are attributable to anesthesia complications.⁴

Choice of pain control measures during surgical abortion is driven by patient preference, risks, costs, effectiveness and provider choice or bias.^{8,9} Because aspiration abortion is a short procedure and pain returns to baseline within 30 minutes,⁶ paracervical block may be preferred by providers as it does not increase procedure or recovery time and is associated with lower morbidity than sedative anesthesia. However, paracervical block has been shown to have limited efficacy in reducing pain during aspiration abortion,¹⁰ and has itself been shown to be painful.¹¹

Non-pharmacologic adjuncts to local anesthetic regimens represent an opportunity for clinicians to improve pain control without increasing risk or cost. Recent national surveys of abortion providers indicate that a significant proportion use local anesthetic along with relaxation techniques such as focused breathing, visualization, vocal coaching and positive suggestion, commonly described as the “vocal local.”^{9,12,13} The prevalence of this practice suggests providers see some benefit to these techniques.

Factors such as young maternal age, nulliparity and a history of dysmenorrhea are associated with higher pain scores during first trimester abortion.^{6,8,12} In addition to

these physiologic predictors of pain intensity during abortion, there is evidence that psychosocial factors may also be associated with pain during abortion.^{5,6,14,15} These psychosocial predictors include pre-procedure anxiety, fear of pelvic exams and blood loss, a sense of stigmatization or isolation, and self-assessed low tolerance for pain. Of these, pre-procedure anxiety has most consistently been associated with higher pain scores. An appreciation for the impact of these non-physiologic mediators of pain serves as the foundation for non-pharmacologic interventions.

The goal of this review is to identify areas of consensus in the literature regarding predictors of pain during first-trimester aspiration abortion and the efficacy of non-pharmacologic pain control adjuncts during these procedures and to suggest techniques that warrant further study.

II. Methods

2.1 Criteria for Eligible Studies

The review included all interventional and observational trials written in any language of first-trimester surgical abortion which evaluated predictors of pain and non-pharmacologic pain management adjunctive therapies using validated pain scales (visual analog scales (VAS), numerical rating scales (NRS), and categorical pain scales (such as Likert scales)). Due to the small number of studies in this area, both randomized and non-randomized studies were included, and we did not restrict studies to specific publication dates. Studies included in the final analysis were published between 1989 and 2014. Studies of pain management for abortions later than 14 weeks gestation were excluded, as these are typically done under sedation and adjunctive therapies are less commonly employed. Studies that did not utilize a standardized pain management tool were also excluded.

The primary outcomes of interest for this review were to define psychosocial predictors of pain intensity during abortion and to compare pain and anxiety measures among women receiving adjunctive pain management therapies during first trimester surgical abortion.

2.2 Search Methods

Articles were identified through a systematic search of the NCBI PubMed database and Google Scholar using the following search terms in various combinations: abortion, pain, non-pharmaceutical, non-pharmacologic, anxiety, fear, pain management, pain reduction, anxiety reduction, complementary and alternative medicine, and integrative medicine. Additional studies were identified from references of primary articles.

2.3 Data Extraction

Articles were reviewed and entered into a matrix for comparison. Data extracted from each article included study design, independent and dependent variables, primary outcome, power and sample size, results, strengths, and limitations.

2.4 Quality Assessment:

Because of the limited number of randomized controlled trials, we included some articles that did not meet CONSORT guidelines.¹⁶ These articles provided descriptions of both predictors of abortion pain and non-pharmacologic pain therapies. Limitations in the reproducibility of findings based on the study design and implementation information provided by the authors are noted.

2.5 Analysis

Studies were divided into two groups for comparison and review: 1) studies evaluating non-physiologic predictors of pain during first trimester abortion and 2) studies evaluating non-pharmaceutical pain management techniques used in first trimester abortion.

III. RESULTS

3.1 Studies evaluating predictors of pain among women having first trimester surgical abortion

Three studies assessing these relationships were identified in our review. The findings of these three studies indicate a consistent relationship between pre-procedure

psychosocial factors and pain experienced during abortion. Understanding these mediators of pain serves as a theoretical foundation for the use of non-pharmacologic pain control adjuncts as a pain management technique.

1) Belanger and colleagues⁵ aimed to identify the factors most predictive of increased pain during a first trimester surgical abortion. The study was conducted with 109 patients ages 13 to 34 years presenting for first trimester abortion in a setting where abortions were done without sedation. Participants were excluded if they did not speak the primary study languages (French or English) or if they displayed “major psychiatric symptomatology”, a term which was not defined by the authors.

The investigators used several validated pain scales, including the McGill Pain Questionnaire and both VAS and verbal pain scales, to capture the “multidimensional” experience of pain. To measure predictors theorized to influence pain experienced during abortion, participants pre-operatively completed the State-Trait Anxiety Inventory (STAI), Beck Depression Inventory, and VAS scales to evaluate moral conflict, ambivalence, fear of judgment, pain concerns, and self-perceived pain tolerance.¹⁷ Participants completed pain scales twice during the procedure and at 15 and 30 minutes post-procedure. The investigators identified several key predictors of increased pain during abortion: pre-procedure depression, anxiety, “moral concerns” and self-described lower pain tolerance.

Belanger and colleagues argue that these findings should serve as guidelines for tailoring the counseling and anesthesia/analgesia options offered to each patient. The findings of this observational study are in agreement with observations reported in prior studies¹⁸ and are aligned with theoretical understandings of the mediators of pain.¹⁹

2) Pud and Amid¹⁴ looked at both state and trait anxiety as predictors of pain among women undergoing abortion. This non-randomized prospective trial had women complete the STAI before their procedure and a VAS rating pain at 15, 30, and 60 minutes post-procedure. The authors found a significant concordance between pre-procedure anxiety and pain (state-anxiety: 83.8% concordant, $p=.024$, trait-anxiety: 89.7%, $p=.013$). Other predictors analyzed in the regression model, including patient age, gestational age, and obstetric history were not significantly related to pain. An important distinction between this study and others reviewed here is that patients were

under anesthesia (propofol) and therefore were unable to report pain during or immediately after their procedure. This is substantially different than many clinical scenarios in which non-pharmacologic pain adjuncts would most commonly be used, and the pain scores collected in this study may be more reflective of post-procedural discomfort than of the acute pain experienced during a pregnancy termination. Regardless, this data does support the findings of other researchers regarding the close relationship between anxiety and pain.

3) Singh et al ¹⁵ hypothesized that pain during surgical abortion would differ based on the suction type employed by the physician (manual vacuum aspiration (MVA) or electric vacuum aspiration (EVA)). In their study of 144 women randomized to either MVA or EVA, no differences in pain were seen based on suction type. However, among women who anticipated a high amount of blood loss for their procedure, pain was significantly higher (OR 4.78 (1.03-22.27)). Conversely, reporting no fear of pelvic exams was protective against reporting higher pain scores (OR 0.23 (.06-.89)). Here again a relationship between anxiety about a potential negative outcome (excessive blood loss) and pain reported during the procedure was demonstrated.

3.2 Studies evaluating non-pharmacologic pain management therapies

Seven studies that met the criteria for this outcome were included. These studies used the following adjunctive therapies: music, hypnosis, aromatherapy, sensory information counseling, relaxation and imagery exercises, and abortion doulas. Only the use of music as an intervention was studied by more than one investigator; all other therapies were assessed in only one study. Comparison between studies therefore is focused on the commonly shared outcomes of pain and anxiety as reported on VAS, NRS, or Likert scales.

As shown in Table 1, no adjunctive therapies reviewed here had significant associations with the primary outcome of interest (reductions in pain and anxiety scores). However, as will be discussed below, most of the therapies were described by the participants as a positive addition to their care.

1) Hypnosis: Marc et al²⁰ conducted a non-blinded randomized controlled trial to assess the effectiveness of hypnotherapy as a pain-reduction adjunct. All women in

the study received pre-operative non-steroidal anti-inflammatory drugs (NSAIDs) and a lidocaine paracervical block. Patients were also able to request administration of mild sedation (intravenous fentanyl and midazolam) at any point and for as long as desired during the procedure; clinicians could also initiate conscious sedation for patients as they deemed necessary.

At 20 minutes pre-procedure, those in the intervention group underwent standardized hypnosis conducted by a trained hypnotherapist, who then provided direct suggestion to reduce pain during the procedure. Women in the control group had a family planning nurse at the bedside who provided reassurance and comfort throughout the procedure. The primary outcome for this trial was frequency of conscious sedation administration in the hypnosis versus standard treatment group, with a secondary outcome of non-inferiority for pain and anxiety between the treatment and control groups measured at time of suction. The study recruited 350 women (176 control, 174 hypnosis) and was powered to detect a 15% difference in requests for conscious sedation and to conduct a non-inferiority assessment of a 5 point difference in pain and anxiety scores between the two groups.

Patients in the control group received sedation 22% more frequently (chi-squared $p=0.0001$, CI 13-32%) than those who received hypnosis. The vast majority of sedation analgesia doses in both groups were requested by the patient, rather than the provider (95% of requests among the hypnosis group, 92% in the control group, $p=0.27$). The intervention demonstrated non-inferiority for pain based on the authors' criteria (difference 2.43, 95% inferior CI -2.28, $p=.0048$) but not for anxiety (difference, -1.20, 95% inferior CI -6.06, $p=.0992$).

A few key limitations of this trial should be noted. First, because patients were not blinded to their assignment, the Hawthorne or placebo effects may have artificially lowered the frequency of requests for sedation in the hypnotherapy group. Another major limitation of this study was the administration of NRS scales to patients who had received sedation analgesia; one-hundred and eleven (31.7%) patients stated that they did not recall reporting pain or anxiety scores during their procedure. The authors describe this phenomenon, and report a statistically significant difference in recall of providing scores between the intervention and control groups (73% of women in

hypnosis group failed to recall versus 61% in the control group, $p=.02$) but do not elaborate on how this may have affected the comparability of the scores. The authors also note the possibility that selection bias may have affected results as women who declined to participate indicated discomfort with the concept of hypnosis, but the authors do not describe how frequently this reason was given for study refusal among screened women.

Though hypnotherapy may reduce the need for additional sedation, incorporating hypnotherapy into clinical practice requires trained hypnotherapy professionals. Quality assurance may not be available in all areas and the additional costs associated with hypnotherapy are unlikely to be recouped through insurance reimbursement.

2) Aromatherapy: Weibe et al (2000)²¹ completed a double-blind randomized controlled trial of 66 patients evaluating the use of aromatherapy with the essential oils vetivert, bergamot, and geranium as a mechanism for reducing anxiety before abortion. In an attempt to preserve blinding, the investigators chose not to use essential oils with more evidentiary basis (such as lavender) as these were more likely to be recognized by participants. Patients were randomized to either the intervention, sniffing essential oils for ten minutes, or the control, sniffing placebo (hair conditioner) for ten minutes. The primary outcome was a 1-unit difference in anxiety reported on a verbal rating scale. Patients completed a VRS of anxiety prior to the intervention and again at the completion of the 10 minute placebo or essential oil aromatherapy session. Change in anxiety was not statistically different between the two groups.

The authors note that their selection of essential oils was based on expert opinion but did not have any evidence of these oils effectiveness as anxiolytics. It is also important to note that the nearly equivalent decrease in anxiety between both groups may be a reflection of placebo or Hawthorne effects, or a result of the participants in both groups spending ten minutes deep-breathing prior to their procedure, a practice which promotes relaxation and likely a reduction in anxiety irrespective of the use of aromatherapy. The authors also do not distinguish how aromatherapy using non-evidence based essential oils and sniffing hair conditioner differ in their presumed effect.

3.) Music as Analgesia: Two randomized controlled trials evaluated the use of music as an adjunctive therapy for pain control during surgical abortion. Wu et al ²² reported on a pilot randomized controlled trial wherein all participants received NSAIDs plus support of a “healthcare assistant” who gave guidance on breathing exercises and provided physical support (hand-holding, etc.). Those randomized to the intervention also listened to music on a handheld MP3 player, choosing from five pre-loaded tracks with the volume controlled so patients could still hear their clinician and healthcare assistant. The genres of music available were classical, pop, jazz, new age, and hip-hop. The primary outcome for this study was pain as reported on a NRS, with secondary outcomes evaluating differences in anxiety, satisfaction and “coping” between the two groups; the authors did not describe an anticipated difference in scores or a power calculation for this pilot test.

Twenty-six women were randomized, 13 in the control group and 13 in the intervention group. No difference in pain scores was seen between groups, though a non-significant trend ($p=0.065$) toward lower anxiety in the intervention group was noted. Investigators found a statistically significant difference in coping scores between groups, with a mean of 8.5 (SD 2.3) in the music group compared to a mean of 6.2 (SD 2.8, $p= .05$) for controls. In addition, the large majority (69%) of qualitative responses regarding factors that helped the patient cope identified the healthcare assistant and the verbal or physical support provided as the most important factor; only 12% of patients stated that the music alone helped them cope. As noted by the authors, this pilot study was likely underpowered to detect differences in mean scores, however the authors do not describe how their sample size was derived. This small sample limits interpretation of the findings. Additionally, the coping measure was derived using a non-validated instrument.

Guerrero et al ²³ also randomized patients to either music played through headphones during the procedure or standard care. The primary outcome for this study was increase in mean pain score between a VAS completed pre-procedurally and immediately post-operatively. The study was powered to detect a 15mm difference in pain scores between the control and intervention groups and enrolled 101 women (47 control, 54 intervention). Participants also completed baseline and post-operative

anxiety scales and vital signs were monitored to provide an objective measure of pain. The music players were pre-loaded with playlists from genres derived from music preference surveys conducted in this clinic's patient population and included rock, pop, hip-hop/rap, classical, jazz, Spanish/Latin, alternative, easy listening, and reggae.

This study found that the group that listened to music experienced higher levels of pain than the control group, with a mean increase in pain of 39.3 (SD 30.1) in the control group and 51.0 (SD 27.6, $p=0.045$) for the intervention group. Anxiety scores did not differ between the two groups, nor did heart rate or blood pressure. High levels of satisfaction with pain control during the procedure were reported by both groups, and despite the contrary findings in VAS measures, a large proportion of patients in the intervention group indicated in open-ended questions that listening to music reduced their pain (63%) and anxiety (67%). A vast majority, 91%, of intervention group participants thought listening to music during abortions was a good idea, with 93% reporting that they would listen to music again during an abortion.

The authors did note the possibility that the music genre selected most commonly by patients, Latin music, has a fast tempo and participants often played it at a high volume. This may partly explain why these studies differed in their findings when compared with prior studies of music as an analgesic in other acute pain settings. Those studies suggest that music of a slow tempo played at low volumes is most efficacious as an analgesic.²⁴

Both studies used the Gate Theory²⁵ of pain as the underpinning of their intervention, relying on distraction to reduce both anxiety and pain. However, the authors of both studies noted that listening to music on headphones may have interfered with patients' ability to communicate with and take cues from their providers and staff, impeding providers or staff from providing anticipatory guidance and suggestions to the patient throughout the procedure. Additionally, both authors mentioned the potential limitations of loading the music players with pre-determined musical selections, thereby restricting participants' choice to genres that may not have produced an anxiolytic effect.

4) Sensory Information: Wells²⁶ investigated the relationship between pre-procedure provision of "sensory information" and a reduction in pain-related distress

during abortion. The theoretical foundation of this study is the perceptual-motor theory of emotion, which posits that the body learns responses to experiences based on its interpretation of the event as sensory (objective) or emotional (subjective). Sensory information counseling attempts to prepare women for their procedure by providing neutral and objective information about the physical sensations experienced during abortion to promote an objective, less emotional representation of the physical experience of the abortion. This is intended to replace negative emotional associations with neutral associations and in turn reduce distress. The authors point out that this theory does not propose a reduction in the physical pain experienced but instead a reduction in the distress related to pain.

This multi-factorial design enrolled 84 women to receive either sensory information counseling or placebo (general information about the procedure with no specific sensory information), and also assessed differences in pain based on anesthesia type (paracervical block plus IV sedation or paracervical block alone). Patients completed a VAS scale measuring distress and pain both pre-and post-operatively, and the STAI prior to the procedure. An observer blinded to group assignment completed the Distress Checklist, a measure of four observable characteristics of distress, facial expression, posture, verbalization and vocalization, during the abortion. Similar to other studies, pre-procedure anxiety was significantly correlated with both VAS distress scores ($r=0.25$, $p=.001$) and distress recorded by the observer ($r=0.22$, $p=.001$). The authors also noted that anesthesia method was significantly associated with pain levels and therefore controlled for anesthesia type in all hypothesis testing.

The intervention had no significant effect on pain levels, patient-reported distress, or observer-recorded distress. The randomization mechanism for this study was not well described and the authors noted a high study participation refusal rate (75%) but do not describe how this impacted their sample, and did not describe a power calculation for detecting differences between their intervention groups. It is unclear if the study had sufficient participants to observe between-group differences.

6) Imagery and Relaxation Techniques: Wells (1989)²⁷ also investigated the use of relaxation and guided imagery techniques for reducing pain during abortion. This

study, based on the Gate Theory of pain and applying cognitive behavioral strategies, suggested that because pain is a multi-dimensional experience, it can be reduced by mitigating one or more dimensions of the painful experience. The three approaches employed in the study, pleasant imagery (guided imagery through a beach or mountain scene), analgesic imagery (concentrating on location of pain and focusing on feelings of numbness or cold), and relaxation (via a head-to-toe relaxation exercise) which the authors note had previously been demonstrated to be effective at reducing pain in acute pain scenarios. Participants in the control group received the “attention control” technique, in which a patient is instructed to think only about techniques they had personally used to successfully reduce acute pain perception in a previous setting and are encouraged to use the same techniques during their procedure.

Pain scores were recorded as both pain sensation intensity and distress associated with pain, both on a 10-cm graphic rating scale. The forty women participating in the study were evenly divided into four groups, although group assignment method is not described in the manuscript. No significant differences were found among pain scores, distress, procedure time, recovery time, or use of analgesics post-procedure based on group assignments. The author did not disclose any power calculation for measuring group differences and it is likely the study was underpowered to detect the small effects seen in comparable studies. The authors describe that the four treatment groups did not differ significantly in obstetric history, use of the assigned strategy during the procedure, or procedure length, but do not mention other potentially confounding differences, such as patient age, obstetric history, or baseline anxiety ratings. This study also had a high refusal rate, with 71% of eligible patients declining participation.

7) Doula support during abortion procedures: Chor and colleagues²⁸ looked at the use of abortion doulas during abortion to reduce pain. This randomized controlled trial was powered to detect a 20% difference in pain scores rated on a VAS. Secondary outcomes were procedure duration, provider-rated procedure difficulty and patient satisfaction. Participants in both groups received the same standard of care for the procedure (misoprostol and ibuprofen) although paracervical block was provided “at the discretion of the provider.” Patients randomized to the doula support had a pre-

procedural counseling session with the doula wherein the role of the doula was presented and patients were encouraged to express their preferences for the types of support offered during the abortion. The doula then provided support accordingly throughout the procedure.

Doulas completed a multi-day training before working with patients. Of the 214 women enrolled in the study, 106 were randomized to doula support and 108 randomized to control. The VAS was collected at three points: pre-procedure, at procedure completion, and approximately 10 minutes post-procedure in recovery. Anxiety and anticipated pain scales were collected pre-procedure. Satisfaction measures were collected post-procedure. No differences were detected in post-procedure VAS scores between the two groups (doula: mean 68.2, SD 28.0, control 70.6, SD 23.5 $p=0.52$). Satisfaction scores also did not differ between the two groups, however women in the doula group advocated strongly (96%) for the routine use of doulas during abortions, and 60% expressed an interest in becoming a doula themselves. A significant difference was demonstrated in the need for additional staff support during the procedure between the two groups, with 2.9% of the intervention group and 14.7% of patients in the control group requiring additional staff support ($p=0.002$). The authors noted that this difference could be attributed to the doulas fulfilling the additional support needs of patients during the procedure. This study was not powered to look at subgroup differences in predictors of pain such as obstetric history or by receipt of paracervical block, though the authors note that the intervention and control groups were similar across these factors.

IV. DISCUSSION

Research indicates a clear relationship between emotions such as fear and anxiety with pain during abortion. Qualitative studies involving in-depth interviews with abortion patients reveal the large impact that a welcoming, supportive, and patient-centered approach can have on a patient's overall perception of their abortion experience.^{29,30} These qualitative assessments also indicate that poorly managed pain colors patients' memories of their abortion negatively.^{29,30}

Despite the biological plausibility and the anecdotal associations that are known to exist between psychosocial characteristics and pain outcome, the interventions reviewed here did not result in significant reductions of pain and anxiety scores, our primary outcome of interest. Several elements may explain the limited efficacy demonstrated in these trials, particularly in light of the positive comments many participants made about their experience with the interventions.

The first potential problem is that of measurement: VAS, NRS, and Likert scales do not provide a comprehensive measure of pain or anxiety and are administered at investigator-derived intervals. The intervals chosen by investigators to measure pain and anxiety may not be the best intervals for capturing pain accurately, and the discordant times and methods used to collect this data across studies makes efficacy comparisons across trials a challenge.

The second factor that may have influenced the relationship between these interventions and pain and anxiety measures is the fact that the interventions used in the trials were investigator-derived and may not have been relevant to the participants. An important aspect of anxiety is the perceived lack of control over impending threats.¹⁹ Engaging patients in a process by which their unique concerns and preferences are addressed could be expected to increase perceived control over their situation, reducing anxiety and therefore mediating pain. As noted by authors of some of these studies, assigning participants to an intervention may not have increased the patient's sense of participation or control in their abortion, which may have reduced the interventions' impact on anxiety.

A consistently positive finding across several studies was the relationship between support personnel, pain and anxiety. While a statistical difference in pain was not seen among patients receiving doula support, their counterparts in the control group did require "additional staff support" at a significantly higher rate. Likewise, patients in the Wu music study reported that the support of staff members during the procedure was the factor most associated with an improved sense of coping, and the authors posited that the musical intervention may have actually limited the benefit of this support by creating a barrier between patient and support staff.

In the qualitative studies referenced above, patients consistently described the support and kindness offered by clinicians and staff as powerful tools for reducing anxiety, isolation, or fear. This concept is also reflected in foundational clinical guidelines used as standards of care for abortion services, which advocate for a comprehensively supportive and compassionate environment in the abortion clinic, from receptionist to clinical staff to clinician, as a tool for reducing pain.^{8,12} Systematically investigating the relationship between supportive environments and abortion pain and anxiety seems to be a promising area of future research.

Abortion and pain are complex and independently challenging for clinical research. The studies presented here reinforce the concept of abortion as a multidimensional experience with both emotional and physical factors affecting pain. Despite the lack of clear evidence of the effectiveness of any individual integrative measure, participants described a positive experience with non-pharmacologic interventions. Women found value in many of these interventions, and for that reason, ongoing investigation into these and similar methods is of significant public health importance.

CHAPTER TWO: A RANDOMIZED CONTROLLED TRIAL OF PATIENT-CENTERED NON-PHARMACOLOGIC PAIN MANAGEMENT TECHNIQUES

I. Introduction

As detailed in Chapter 1, family planning researchers and clinicians are interested in improving pain control during first trimester surgical abortion without substantially increasing patient risks or healthcare cost, yet trials of non-pharmacologic techniques to reduce pain during first trimester abortion have not been shown to be effective. One explanation for the limited efficacy seen in these studies is that these non-pharmacologic pain management techniques, which were investigator derived and prescribed to the patient, did not sufficiently involve the patient in the pain management process.

Recognizing this limitation, a hypothesis was proposed that the most important component of effective non-pharmacologic pain relief is not the specific intervention, nor the practitioner, but instead that the patient participates in a process of choosing a non-pharmacologic pain management technique that best suits her. Considering this, it was proposed that actively and compassionately engaging patients in their own care during a procedure that may be unfamiliar, emotional, and marginalizing would have a significant impact on anxiety and therefore could result in a reduction in pain scores. This study aimed to identify a patient-centered, low cost, low risk mechanism for improving pain control during first trimester surgical abortion.

II. Materials and Methods

This was a randomized controlled trial conducted at the Women's Options Center at the University of Hawaii Department of Obstetrics, Gynecology and Women's Health in Honolulu, Hawaii. This study was conducted according to prevailing ethical principles and was approved by the University of Hawaii Human Studies Program Institutional Review Board, CHS 22893 and was registered at [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02590146) (NCT02590146). The study period was November 2015 through July 2016.

This clinic is staffed by 4 ob-gyn attending physicians, 2 family planning fellows, and 1 rotating first year ob-gyn resident. Standard office practice for first trimester

surgical abortion pain management includes administration of an NSAID, usually 800 mg ibuprofen administered orally, at least 10 minutes before the procedure. Patients then receive a paracervical block containing lidocaine at the start of the procedure. Physicians also use some form of verbal coaching and reassurance as deemed appropriate or necessary per patient.

2.1 Eligibility and Randomization

Patients were eligible for participation if they were at least 14 years old, English-speaking, and requesting an in-office surgical abortion or miscarriage management for a pregnancy at 13 weeks and 6 days or less. Patients ages 14-17 required parental consent for participation in the study. Patients who requested that a companion be present for the procedure were not eligible for study participation. All patients first consented to a surgical in-office abortion before being approached for study participation.

Patients were randomized using computer-generated blocked random assignment conducted by a statistician not associated with the study. Randomization assignments were placed in opaque, sealed envelopes and opened by one of two investigators after obtaining participant consent for the study. To minimize placebo effect, participants were not informed of the primary hypothesis of the study during the consent process. They were instead informed that the investigators were interested in identifying effective non-pharmacologic pain management techniques. Patients were told the purpose of the study was to compare the effectiveness of various non-pharmacologic pain management options versus standard office practice, which consisted of providers “talking through” the procedure.

2.2 Intervention

The study proceeded as follows: all patients received a standardized pre-procedure counseling session with one of two investigators wherein the procedure was described, step-by-step, in relation to sensations and discomfort that could be expected. Patients in the control group then had a surgical abortion according to standard office protocol as described above.

Patients in the intervention group had a pain-control strategy discussion after the standardized counseling, wherein patients were asked to recall previous procedures or instances of acute pain and to recall the techniques they found helpful in managing that pain. The investigator then encouraged the patient to reflect on that experience and use those tools to alleviate discomfort during the abortion. This counseling used the structure recommended by Maltzer et al,⁸ which focuses on validating concerns and providing reassuring guidance and correction to misconceptions, and then segued into a collaborative discussion about the non-pharmacologic pain management techniques available to the patient.

These techniques included ambient music of the participant's choice played during the procedure, physical contact (hand or shoulder holding) during the procedure, provider step-by-step narration of the procedure, a recording of a guided imagery meditation, or a recording of a focused breathing exercise. Participants could choose one or multiple of these pain management adjuncts, or they could propose their own alternative methods. Emphasis was placed on participant choice. After choosing their preferred pain control adjunct, the abortion otherwise followed the same standard protocol as described for the control group.

2.3 Data collection:

All patients completed a visual analog scale (VAS) to assess baseline pain and a VAS to assess baseline anxiety. Patients also completed the State-Trait Anxiety Inventory (STAI). Demographic information and an abbreviated medical history were collected to allow for analysis controlling for known predictors of increased pain during abortion, such as patient age, gestational age and history of vaginal delivery.^{5,15} As many patients in Hawaii identify as multiracial, participants were able to select every race category they identified with in addition to selecting their ethnicity (Hispanic/Latino or Non-Hispanic/Latino). Suction type, provider gender and medical trainee (fellow, resident, or medical student) involvement variables were recorded at the time of surgery to allow for analysis of these potential confounders.^{15,31}

Immediately following the completion of the procedure, women in both the intervention and control groups were asked to complete a VAS measuring overall pain.

At ten minutes post-procedure participants completed a VAS of current pain and overall satisfaction with their pain management during the abortion, and those in the intervention group were asked to rate their satisfaction with the pain management adjunct(s). These data points were collected by a member of the study team who had not participated in the pre-procedure counseling or intervention administration to limit social desirability bias. Length of procedure (speculum insertion through speculum removal, or until initiation of IUD insertion) was also recorded, and providers completed a Likert scale evaluating procedure difficulty and a VAS estimating patient pain level after the procedure. There was no ongoing follow up with participants after their procedure day.

2.4 Sample size and statistical analysis:

The primary outcome of interest was the difference in pain scores between the intervention and control groups on the immediate post-procedure 100mm VAS scale. A 20mm difference was deemed to be clinically significant. To find this difference with 80% power and a two-sided alpha of .05 required 34 participants per group. In anticipation of potential patient drop-out of 10%, an additional 6 participants were recruited for a total of 74 participants.

Secondary outcomes of interest included pain at 10-minutes post-procedure, overall satisfaction with pain control, procedure length, and provider's rating of overall procedure difficulty. Primary and secondary outcomes were analyzed using chi-squared or Fisher's Exact, ANOVA, or student's t-tests. All analyses were completed using SPSS 24 (SPSS, Inc. Chicago, IL).

III. Results

During the study period, a total of 157 women presented for in-office surgical abortions (Figure 1). Of these, seven patients could not be screened for eligibility due to logistical constraints with study or clinic staff. Of the 150 patients screened, 50 (33.3%) were excluded, and 26 (17.3%) declined participation. The most common reason for exclusion was patient request for a companion in the room (43 patients, 86% of ineligible patients), and the most commonly stated reason for declining study

participation was disinterest in talking to research staff and a desire to “just get it over with.” In total, 74 women were enrolled and randomized. No patients dropped out or were lost to follow up.

No significant differences in patient demographics, obstetric history, anxiety scores, or aspiration type or procedure length were seen between the control and intervention groups (Table 2). Participant age ranged from 17-45 (mean age 29) with a gestational age ranging from 28-94 days (mean 59 days). The majority of participants reported Asian (50.0%) and Native Hawaiian/Other Pacific Islander (37.8%) as their race and 6.8% reported Hispanic/Latino ethnicity. The majority of procedures were completed by first year ob-gyn residents (37.8%) and family planning fellows (40.5%). Both residents and fellows were directly supervised during procedures by attending physicians.

Procedures wherein the provider noted a complication did not differ significantly between the groups and were minor in nature and unrelated to the intervention (Table 2). Complications included cervical stenosis, uterine fibroids, symptoms of intravascular lidocaine administration, and a broken cannula.

A Q-Q plot demonstrated that pain scores were normally distributed. We found no difference in overall pain scores between the two groups (Table 3). The mean pain score was 61.9 (SD= 27.0, median 62.7, range 1.5-100). Satisfaction with overall pain control scores was left-skewed, and also did not significantly differ between groups, with a median score of 79.5 (mean 70.5, (SD=31.1) range 0-100). Ten minute pain, procedure length and physician assessment of procedure difficulty also did not differ between groups. Physicians’ average score of perceived patient pain was substantially lower than the average reported by participants (physician estimate of pain mean score: 46.3, patient average pain mean score: 61.9).

For the purposes of analysis of the individual interventions, participants were stratified into either the category of “multiple interventions” or a single intervention (Table 4). Fifteen participants (20.3%) chose multiple interventions. Among patients who chose only one intervention, music was the most frequently chosen (13/22, 59.1%). Mean overall pain scores were lowest in the group selecting physical contact and above the mean among participants selecting multiple interventions, provider narration, and

guided imagery. ANOVA analysis showed no significant difference in mean pain scores between the interventions (not shown). When compared to other participants in the intervention group, those who selected multiple interventions had higher trait anxiety scores on the STAI (multiple techniques' mean score: 42.3, all others' mean score: 33.9, $p=0.06$).

IV. **Discussion:**

Giving patients a choice in non-pharmacologic pain management adjuncts did not significantly reduce pain scores in our study population. Participants in both groups' mean pain scores were similar to the pain scores reported in other studies of women having first trimester office-based abortion with a paracervical block.^{23,28} Also consistent with other studies, participants' pain scores dropped substantially within ten minutes of procedure completion.⁵ Physicians in our study underestimated participant pain levels as has been noted in other studies.^{6,15}

Participants in both the intervention and control groups reported high satisfaction with the pain management provided during the procedure. Offering patients a choice of non-pharmacologic pain management adjunct did not result in significant differences in procedure length, complication rates, or difficulty of cases.

The most frequently selected intervention in the treatment group was ambient music. The popularity of music as an intervention mirrors the qualitative findings of the music studies conducted by Guerrero and Wu, whose participants reported that music was a positive addition to their care and something they would request in the future, even though the music was not associated with lower pain scores.

Patients who selected physical contact reported the lowest pain scores. As discussed in Chapter 1, extra support from a compassionate staff member can have meaningful impacts on a patient's experience. In Chor's study evaluating the effect of abortion doulas, women in the control group required added staff support, usually a medical assistant who came into the room to hold the patient's hand or otherwise provide physical support, at a statistically significantly higher rate than women who had doula support. Chor suggested that routine use of doulas could fulfill this frequent request for physical support.²⁶ Similarly, in Wu's music study, participants noted that it

was the supportive staff at the bedside that was the most influential component of a positive perception of the abortion visit.²² This also echoes the themes that emerge in qualitative research that indicate kindness and supportiveness are key components of positive experiences for abortion patients.²⁹

Patients who selected multiple interventions had higher than average pain score higher trait-anxiety scores than other participants. Trait anxiety is reflective of an individual's general sense of anxiety, outside of any particular stressor. Women who had higher general anxiety may have had a greater anticipation of pain or a reduced sense of self-efficacy in managing pain. A patient who requests multiple supportive techniques could generally have higher than average anxiety and could warrant a more supportive approach in their clinical care.

The findings of this study can be considered within the concept of “decision fatigue” or the “paradox of choice”.^{32,33} These theories propose that an individual has a finite amount of energy and cognitive capacity for decision making each day and over time will value the presentation of options less and less. In the setting of a typical abortion visit, a patient is faced with a large number of decisions, each of which is discussed in detail during the visit. These choices span the entire abortion encounter, and include the decision to terminate, method of termination, and preferred contraceptive method post-procedure. By the time investigators presented the additional choices available in the study to participants, they may have reached decision exhaustion and therefore not experienced any of the positive associations hypothesized to result from this increased personalization of their care.

There were several logistical limitations that could have impacted our findings. First, approximately a third of eligible patients were excluded from study participation, and the vast majority of those patients were excluded because they preferred to have a companion in the room with them during the procedure. When designing the study, it was decided that companions could interfere with administration of the non-pharmacologic adjuncts and that the presence of a companion could introduce biases that could not be controlled for in statistical analysis. As there was a large proportion of our patient population that preferred to have a companion in the room, future research should consider if the presence of companions can be leveraged to support better pain

management. Because demographic information about patients who declined or were ineligible was not collected, it is possible that there are unrecognized selection biases resulting from unknown differences between these women and those who participated in the study.

As discussed in Chapter 1, accurate measurement of pain is a challenge and no single tool or time point is uniformly used across abortion studies to measure pain. While the VAS may be an imperfect mechanism for evaluating pain in this setting, it is a validated instrument and the most commonly used tool in abortion pain research, which improves the generalizability of our findings. Additionally, in this study, the VAS was administered immediately after procedure completion, which limits the data available and differs from the methodology of other studies. However, collecting multiple data points throughout the procedure would have interrupted the adjuncts being used.

Another meaningful limitation was the inability to standardize how physicians chose to interact with patients in the control group in order to ensure a safe and efficient procedure. Some providers may have an interactive style that promotes patient relaxation and reduces anxiety, thereby minimizing the difference between the experiences of those in the treatment and control groups. Similarly, the use of guided breathing or imagery recordings in the treatment group may have reduced a physician's inclination to provide their typical vocal coaching and reassurance to patients choosing those techniques.

While no differences were seen between the two groups, the interventions provided were low cost, require no extra or specialized personnel, and can be implemented without any impact on patient safety. Offering all patients the option to play ambient music of their choosing in the procedure room or physical contact, such as hand or shoulder holding, are low-cost interventions that do not negatively impact patient pain scores and could increase patient satisfaction. Expanding patient participation to allow for personalization of care, while remaining conscientious about the potential for decision fatigue, is a valuable quality improvement technique even if the effect on pain is neutral.

Table 1. Summary of trials of non-pharmacologic pain and anxiety management adjuncts during first-trimester aspiration abortion

Author, Year	Design	Data Collection Technique	Sample Size	Results	Comments
Chor, J. 2014	RCT Intervention group: Doula support by trained doula plus standard care Comparison group: Standard care only	VAS ^a for pain collected at three intervals: pre-procedure, immediately post-procedure, and 10 minutes post-procedure	214	Mean (SD) post-procedure on Visual Analog Scale Score: Doula: 68.2 (28) Control: 70.6 (23.5) <i>P</i> =0.52	Doula support highly rated by participants. Introduction of doulas to clinic requires resources not available in all settings.
Guerrero, J. 2012	RCT Intervention group: Music played in headphones plus standard care Comparison group: Standard care only	VAS for pain administered pre- and post-procedure	101	Mean (SD) pain change from baseline on Visual Analog Scale Intervention: 51.0 (27.6) Control: 39.3 (30.1) <i>P</i> =0.05	Participants endorsed music's effectiveness at reducing pain despite higher pain scores; genres of music available to patients may not have been conducive to anxiety reduction
Marc, I. 2008	RCT Intervention group: Hypnotherapy plus standard care Comparison group: Standard care only	VNS ^b for pain and anxiety administered at three time intervals: pre-randomization, during pelvic exam, and at time of suction.	350	Mean (SD) pain scores at time of suction on Visual Numeric Scale: Intervention: 39.7 (25.4) Control: 42.1 (27.9) <i>P</i> =0.004 for non-inferiority Mean (SD) Anxiety Scores on Visual Numeric Scale Intervention: 34.3 (27.4) Control: 33.1 (27.6) <i>P</i> =0.10 for non-inferiority	A large proportion of patients did not remember giving pain scores during procedure. Hypnosis did produce significant reduction in request for sedation anesthetics. Implementing hypnosis to clinical practice requires trained personnel and resources.

Abbreviations:

^aVisual Analog Scale- score on a visual analog scale from 1-100 with 100 indicating highest pain or anxiety

^b Visual Numeric Scale – score on a visual numeric scale from 1-100 with 100 indicating highest pain or anxiety

^c Verbal Rating Scale- score on a verbal rating scale from 1-10 with 10 indicating highest pain or anxiety

^d Graphic Rating Scale – score on a verbal rating scale from 1-10 with 10 indicating highest pain or anxiety

^e Verbal Numeric Scale- score on a verbal numeric scale from 1-10 with 10 indicating highest pain or anxiety

Table 1. (Continued) Summary of Trials of Non-Pharmacologic Pain Control Adjuncts for Management of Pain and Anxiety during First-Trimester Aspiration Abortion

Author, Year	Design	Data Collection Technique	Sample Size	Results	Comments
Wiebe, E. 2000	RCT Intervention group: Pre-procedure deep breathing aromatherapy with essential oils Comparison group: Pre-procedure deep breathing with placebo (hair conditioner)	VRS ^c for anxiety before and at the completion of intervention	66	Mean anxiety score change from baseline on Visual Rating Scale: Intervention: 1.0 Control: 1.1 <i>P</i> = 0.71	Essential oils used did not have evidentiary basis; possible that deep breathing alone would produce anxiolytic effect.
Wells, N. 1992	2x2 factorial design: Treatment Group: Sensory information counseling plus standard care Comparison Group: General information about the procedure plus standard care	VAS for pain administered immediately after procedure and 5-15 minutes post-procedure	84	Mean pain score post-procedure on Visual Analog Scale: Intervention: 58.05 (24.25), Control: 59.59 (27.42) No <i>P</i> value reported	Non-randomized trial with no description of group assignments. Power calculation not described. High rate of refusal for study participation.

Abbreviations:

^aVisual Analog Scale- score on a visual analog scale from 1-100 with 100 indicating highest pain or anxiety

^b Visual Numeric Scale – score on a visual numeric scale from 1-100 with 100 indicating highest pain or anxiety

^c Verbal Rating Scale- score on a verbal rating scale from 1-10 with 10 indicating highest pain or anxiety

^d Graphic Rating Scale – score on a verbal rating scale from 1-10 with 10 indicating highest pain or anxiety

^e Verbal Numeric Scale- score on a verbal numeric scale from 1-10 with 10 indicating highest pain or anxiety

Table 1. (Continued) Summary of Trials of Non-Pharmacologic Pain Control Adjuncts for Management of Pain and Anxiety during First-Trimester Aspiration Abortion

Author, Year	Design	Data Collection Technique	Sample Size	Results	Comments
Wells, N. 1989	Non-randomized control: Intervention group: one of four techniques plus standard care; Relaxation, Pleasant Imagery, Analgesic Imagery Comparison group: attention control technique plus standard care	GRS ^d scale for pain and distress completed immediately post-procedure.	40	Mean (SD) pain score post-procedure on Graphic Rating Scale score: Relaxation: 6.77 (2.21), Pleasant Imagery: 5.45 (2.12) Analgesic Imagery: 7.36 (2.08) Control: 5.76 (2.33) $P=0.77$	Group assignment and power calculation not described. High rate of refusal, no description of baseline group differences in psychosocial predictors of pain.
Wu, J. 2012	Pilot RCT Intervention group: Music played in headphones plus standard care Comparison group: Standard care only	VerbNS ^e for pain and anxiety administered at 5 time points	26	Mean pain score across 5 time points on Verbal Numeric Scale: Music: 7.5 Control: 7.2 P -value not reported (described as non-significant) Mean anxiety score across 5 time points on Verbal Numeric Scale Music: 2.4, control: 4.5 $P=0.06$	Pilot study inadequately powered to detect group differences; patients referenced support from staff and courteous, kind treatment most frequently as factor affecting their perception of a positive abortion experience.

Abbreviations:

^aVisual Analog Scale- score on a visual analog scale from 1-100 with 100 indicating highest pain or anxiety

^b Visual Numeric Scale – score on a visual numeric scale from 1-100 with 100 indicating highest pain or anxiety

^c Verbal Rating Scale- score on a verbal rating scale from 1-10 with 10 indicating highest pain or anxiety

^d Graphic Rating Scale – score on a verbal rating scale from 1-10 with 10 indicating highest pain or anxiety

^e Verbal Numeric Scale- score on a verbal numeric scale from 1-10 with 10 indicating highest pain or anxiety

Table 2. Demographics and baseline scores, intervention and control groups

Variable	Intervention N=37 N/Mean(% or SD)	Control N=37 N/Mean(% or SD)	P Value
Age	29.9 (6.9)	28.3 (6.3)	0.30
Race/Ethnicity*			
Asian	19 (51.4%)	18 (48.6%)	0.82
Native Hawaiian/Pacific Islander	14(37.8%)	14 (37.8%)	1.00
White	14 (37.8%)	13(35.1%)	0.81
Black	1 (2.7%)	3 (8.1%)	0.30
American Indian/Alaskan Native	3 (8.1%)	2 (5.4%)	0.64
Hispanic/Latino	2 (5.4%)	3 (4.1%)	0.64
Prior Pregnancy	26 (50%)	26 (50%)	1.0
Prior Delivery	20 (54.1%)	18 (47.4%)	0.64
Gestational Age	59.5 days (16.1)	59.1 days (12.9)	0.92
Prior Surgical Abortion	18 (48.6%)	12 (32.4%)	0.16
History of Dysmenorrhea	4 (10.8%)	7 (18.9)	0.38
Mean Baseline Pain VAS	3.9 (12.1)	1.3 (2.4)	0.20
Mean Baseline Anxiety VAS	32.9 (26.7)	33.2 (28.0)	0.97
Mean STAI Y1 Score	44.6 (10.2)	42.5 (10.7)	0.41
Mean STAI Y2 Score	37.35 (13.6)	35.54 (11.0)	0.53
Provider Level			
Attending	8 (21.6%)	7 (18.9%)	0.77
Family Planning Fellow	13 (35.1%)	17 (45.9%)	0.34
PGY-4°	0 (0%)	1 (2.7%)	1.0*
PGY-1°	16 (43.2%)	12(32.4%)	0.38
Provider Gender Male	5 (13.5%)	5 (13.5%)	1.0
Mean Case Difficulty (scale 0-5)	2.68 (0.92)	2.84 (0.93)	0.45
Manual vacuum aspirator used	29 (78.4%)	28 (75.7%)	0.78
Complication	5 (13.5%)	1 (2.7%)	0.20*

*Percentages equal >100% as participants were allowed to select more than one race

°Post-graduate year (PGY) refers to level of training in obstetrics and gynecology residency. PGY-1 is the first year of training, PGY-4 is the final year.

*Fisher's exact test used

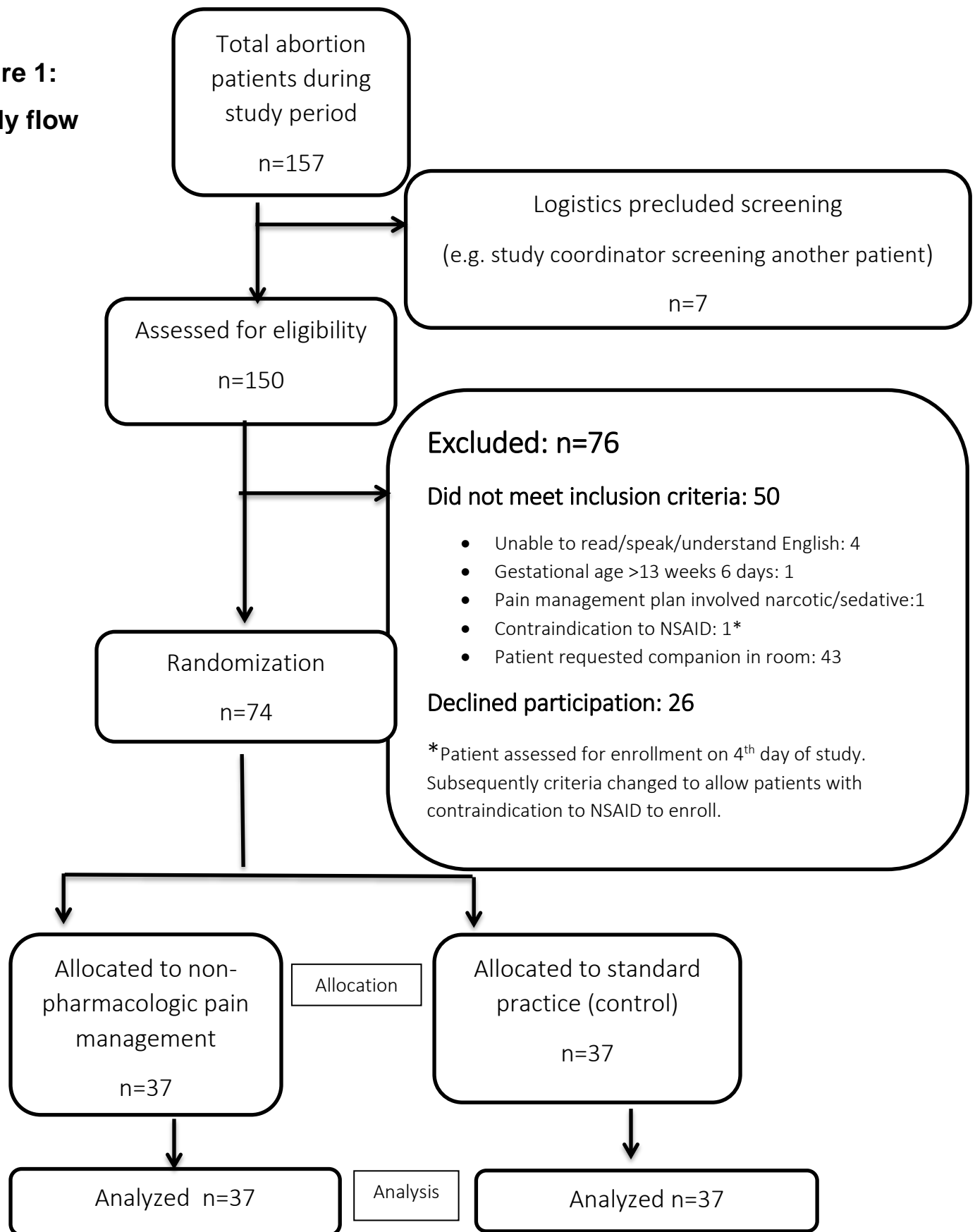
Table 3: Comparison of ten-minute pain, satisfaction, procedure difficulty and procedure length means

Student's T-Tests	Intervention (SD)	Control (SD)	P Value
Mean VAS Score, Overall Pain	63.3 (28.5)	60.6 (28.8)	0.68
Mean pain at 10 minutes post-procedure	27.9 (25.4)	25.4 (23.1)	0.66
Mean overall satisfaction with pain control	72.4 (30.2)	69.3 (32.3)	0.67
Mean provider perception of patient pain	44.0 (17.8)	48.7 (19.2)	0.27
Mean procedure length (minutes)	8.4 (4.8)	8.1 (4.7)	0.75

Table 4: VAS mean scores per Intervention selected

Intervention Selected	Frequency Selected N (%)	Mean VAS (SD)
Physical Contact	3 (13.6%)	34.1 (37.1)
Music	13 (59.1%)	59.9 (31.2)
Provider Narration	2 (9.1%)	76.0 (28.2)
Focused Breathing	0 (0%)	
Guided Imagery	3 (13.6%)	72.3 (24.17)
None	1 (4.5%)	50.5 (n/a)
Multiple Interventions	15 (20.3%)	69.4 (25.0)

Figure 1:
Study flow



APPENDIX A: VAS INSTRUMENT

Baseline pain (before procedure): "What is your level of pain right now?"



Pre-Procedure Anxiety Level: "What is the amount of anxiety/nerves you feel right now?"



Overall Pain Score (1min post-procedure): “What level was your overall pain during the procedure?”



Post-procedure pain (pain level 10 minutes after procedure ended):

“What is your level of pain right now?”



Satisfaction with overall procedure pain control:

“How satisfied were you with pain control for the procedure overall?”



Not at all satisfied

Very Satisfied

Satisfaction with pain control adjuncts (intervention group only): “How satisfied were you with the extra pain management and relaxation techniques we used?”



Providers:

Patient Pain level:

“What was the patient’s pain level overall?”



Compared to the average procedure, was this procedure:



APPENDIX B: LICENSE AND SAMPLE STAI

To whom it may concern,

This letter is to grant permission for the above named person to use the following copyright material for his/her thesis or dissertation research.

Instrument: State-Trait Anxiety Inventory for Adults

Authors: Charles D. Spielberger, in collaboration with R.L. Gorsuch, G.A. Jacobs, R. Lushene, and P.R. Vagg

Copyright: 1968, 1977 by Charles D. Spielberger

Five sample items from this instrument may be reproduced for inclusion in a proposal, thesis, or dissertation.

The entire instrument may not be included or reproduced at any time in any other published material.

Sincerely,

Robert Most Mind Garden, Inc. www.mindgarden.com

For use by Mary Tschann only. Received from Mind Garden, Inc. on October 12, 2015

SELF-EVALUATION QUESTIONNAIRE STAI Form Y-1

Please provide the following information:

Name _____ Date _____ S _____

Age _____ Gender (Circle) M F T _____

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right now*, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

NOT AT ALL
MODERATELY
SOMEWHAT
VERY MUCH SO

1. I feel calm..... 1 2 3 4
2. I feel secure 1 2 3 4
3. I am tense 1 2 3 4
4. I feel nervous 1 2 3 4

SELF-EVALUATION QUESTIONNAIRE

STAI Form Y-2

Name _____ Date _____

DIRECTIONS

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

ALMOST NEVER
SOMETIMES
OFTEN
ALMOST ALWAYS

21. I feel pleasant..... 1 2 3 4
22. I feel nervous and restless 1 2 3 4
23. I feel calm 1 2 3 4

APPENDIX C: DATA COLLECTION INSTRUMENT

Data Collection Form

Non-Pharmacologic Pain Control Adjuncts during First Trimester Abortion:
A Randomized Controlled Study

TODAY'S VISIT

1. Location of procedure (**check one**):
 - a. Kapiolani Suite 801..... ☐
 - b. Queens POB 3, Suite 610..... ☐

2. Level of provider doing majority of procedure (**check one**):
 - a. PGY-1..... ☐
 - b. PGY-2..... ☐
 - c. PGY-3..... ☐
 - d. PGY-4..... ☐
 - e. Family planning fellow..... ☐
 - f. Attending..... ☐

3. Provider gender ☐ Male ☐ Female

4. Patient age: _____

5. Patient Height: _____ ft _____ inches

6. Patient Weight: _____ lbs

7. Gestational age (weeks and days): _____

8. Pre-operative pain medication:
 - a. _____ Ibuprofen (either in office or at home). Dose _____

 - b. _____ Acetaminophen (either in office or at home). Dose _____

9. Time elapsed between NSAID administration and procedure (in minutes): _____

10. Is today's procedure being done for miscarriage management?: ☐ Yes ☐ No

11. Randomization Number: _____

12. Group assignment: _____

13. Pain Management Adjunct Selected (Intervention Group Only):

- ☐ Physical contact (hand/shoulder holding)
- ☐ Music in procedure room
- ☐ Provider procedure narration
- ☐ Focused breathing
- ☐ Guided imagery
- ☐ None
- ☐ Other _____

14. Procedure Length: _____minutes_____seconds

15. Suction type used: ☐ EVA ☐ MVA

16. Complications: ☐ Yes ☐ No

a. **If yes, describe complications:** _____

REFERENCES

1. Pazol K, Creanga AA, Jamieson DJ. Abortion Surveillance - United States, 2012. *MMWR Surveill Summ* 2015;64:1-40.
2. Jones RK, Jerman J. Abortion incidence and service availability in the United States, 2011. *Perspect Sex Reprod Health* 2014;46:3-14.
3. Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. *Obstet Gynecol* 2012;119:215-9.
4. Zane S, Creanga AA, Berg CJ, et al. Abortion-Related Mortality in the United States: 1998-2010. *Obstet Gynecol* 2015;126:258-65.
5. Belanger E, Melzack R, Lauzon P. Pain of first-trimester abortion: a study of psychosocial and medical predictors. *Pain* 1989;36:339-50.
6. Borgatta L, Nickinovich D. Pain during early abortion. *J Reprod Med* 1997;42:287-93.
7. Lawson HW, Frye A, Atrash HK, Smith JC, Shulman HB, Ramick M. Abortion mortality, United States, 1972 through 1987. *Am J Obstet Gynecol* 1994;171:1365-72.
8. Maltzer DS, Maltzer MC, Wiebe ER, Halvorson-Boyd G, Boyd C. Pain management. A clinician's guide to medical and surgical abortion Philadelphia (PA): Churchill Livingstone 1999:73-89.
9. O'Connell K, Jones HE, Simon M, Saporta V, Paul M, Lichtenberg ES. First-trimester surgical abortion practices: a survey of National Abortion Federation members. *Contraception* 2009;79:385-92.
10. Renner RM, Jensen JT, Nichols MD, Edelman AB. Pain control in first-trimester surgical abortion: a systematic review of randomized controlled trials. *Contraception* 2010;81:372-88.
11. Renner RM, Nichols MD, Jensen JT, Li H, Edelman AB. Paracervical block for pain control in first-trimester surgical abortion: a randomized controlled trial. *Obstet Gynecol* 2012;119:1030-7.
12. Stubblefield PG. Control of pain for women undergoing abortion. *Suppl Int J Gynecol Obstet* 1989;3:131-40.
13. Meckstroth KR, Mishra K. Analgesia/pain management in first trimester surgical abortion. *Clin Obstet Gynecol* 2009;52:160-70.
14. Pud D, Amit A. Anxiety as a predictor of pain magnitude following termination of first-trimester pregnancy. *Pain Med* 2005;6:143-8.
15. Singh RH, Ghanem KG, Burke AE, Nichols MD, Rogers K, Blumenthal PD. Predictors and perception of pain in women undergoing first trimester surgical abortion. *Contraception* 2008;78:155-61.
16. Grimes DA. The "CONSORT" guidelines for randomized controlled trials in Obstetrics & Gynecology. *Obstet Gynecol* 2002;100:631-2.
17. Julian LJ. Measures of anxiety: State-Trait Anxiety Inventory (STAI), Beck Anxiety Inventory (BAI), and Hospital Anxiety and Depression Scale-Anxiety (HADS-A). *Arthritis Care Res (Hoboken)* 2011;63 Suppl 11:S467-72.
18. Smith GM, Stubblefield PG, Chirchirillo L, McCarthy MJ. Pain of first-trimester abortion: its quantification and relations with other variables. *Am J Obstet Gynecol* 1979;133:489-98.
19. Tang J, Gibson SJ. A psychophysical evaluation of the relationship between trait anxiety, pain perception, and induced state anxiety. *J Pain* 2005;6:612-9.
20. Marc I, Rainville P, Masse B, et al. Hypnotic analgesia intervention during first-trimester pregnancy termination: an open randomized trial. *Am J Obstet Gynecol* 2008;199:469 e1-9.
21. Wiebe E. A randomized trial of aromatherapy to reduce anxiety before abortion. *Eff Clin Pract* 2000;3:166-9.
22. Wu J, Chaplin W, Amico J, et al. Music for surgical abortion care study: a randomized controlled pilot study. *Contraception* 2012;85:496-502.
23. Guerrero JM, Castano PM, Schmidt EO, Rosario L, Westhoff CL. Music as an auxiliary analgesic during first trimester surgical abortion: a randomized controlled trial. *Contraception* 2012;86:157-62.

24. Nilsson U. The anxiety- and pain-reducing effects of music interventions: a systematic review. *AORN J* 2008;87:780-807.
25. Moayedi M, Davis KD. Theories of pain: from specificity to gate control. *J Neurophysiol* 2013;109:5-12.
26. Wells N. Reducing distress during abortion: a test of sensory information. *J Adv Nurs* 1992;17:1050-6.
27. Wells N. Management of pain during abortion. *J Adv Nurs* 1989;14:56-62.
28. Chor J, Hill B, Martins S, Mistretta S, Patel A, Gilliam M. Doula support during first-trimester surgical abortion: a randomized controlled trial. *Am J Obstet Gynecol* 2014.
29. McLemore MR, Desai S, Freedman L, James EA, Taylor D. Women know best--findings from a thematic analysis of 5,214 surveys of abortion care experience. *Womens Health Issues* 2014;24:594-9.
30. Kimport K, Cockrill K, Weitz TA. Analyzing the impacts of abortion clinic structures and processes: a qualitative analysis of women's negative experience of abortion clinics. *Contraception* 2012;85:204-10.
31. Edelman A, Nichols MD, Jensen J. Comparison of pain and time of procedures with two first-trimester abortion techniques performed by residents and faculty. *Am J Obstet Gynecol* 2001;184:1564-7.
32. Iyengar SS, Lepper MR. When choice is demotivating: can one desire too much of a good thing? *J Pers Soc Psychol* 2000;79:995-1006.
33. Reed DD, Kaplan BA, Brewer AT. Discounting the freedom to choose: implications for the paradox of choice. *Behav Processes* 2012;90:424-7.